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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,032

10/01/2004

Eric Berreklouw

2023-1003

4666

466 7590 02/17/2010

YOUNG & THOMPSON  
209 Madison Street  
Suite 500  
Alexandria, VA 22314

EXAMINER

TYSON, MELANIE RUANO

ART UNIT

PAPER NUMBER

3773

NOTIFICATION DATE

DELIVERY MODE

02/17/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/510,032	<b>Applicant(s)</b> BERREKLOUW, ERIC	
	<b>Examiner</b> MELANIE TYSON	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 59-62 and 65-117 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 59-62 and 65-117 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This action is in response to the applicant's amendment received 02 December 2009. The amendments made to the claims do not place the application in condition for allowance for the reasons set forth below. Claims 63 and 64 are cancelled, and new claims 90-117 have been added.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 59-62 and 65-117 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Claim Objections***

Claim 80 is objected to because of the following informalities: claim 80 contains bullets. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 104 and 113 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 104 recites the limitation "the flange" in line 4. There is insufficient antecedent basis for this limitation in the claim. It is unclear as to what is being claimed in claim 13.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 59, 60, 61, 65-73, 76, 85-92, 96, 105-110, and 113-117 are rejected**

**under 35 U.S.C. 102(e) as being anticipated by Soble et al. (U.S. Patent No.**

**6,547,724 B1).** Soble discloses an assembly (see entire document) comprising a

suction source (vacuum source connects to suction line 20), a stabilizer (10), an

instrument [applicator] (50) having a head section (52) capable of positioning a fixing

device as claimed and removably positioned in the stabilizer, one or more suction

nozzles (distal openings) having ducts (3) in the shape of a loop extending as recited in

the claims (as depicted in Figure 3B), stops (proximal end of 10 and 50) for fixing the

instrument and stabilizer in an axial position with respect to one another, a locking

mechanism or sealing ring (clamp 42) that fixes the position (thus prevents rotation) of

the instrument (for example, see column 5, lines 42-44), a guide (lumen 11), working

duct (1), wherein the vacuum may be applied independently to the nozzles (for

example, see column 6, lines 20-28), the guide may comprise an outer surface of the

instrument, the working duct is flexible and may be curved (for example, see Figure 1),

and Soble's device is capable of performing all the functions as claimed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 62, 74, 75, 81-84, 93, 97, 100-104, 111, and 112 are rejected under 35**

**U.S.C. 103(a) as being unpatentable over Soble et al.**

With respect to claims 62, 74, 75, and 81-84, Soble discloses the claimed invention except for sensors and a scale provided on the guide. However, it is well known in the art to add sensors to medical instruments in order to provide for an additional guide, or navigation means, for locating the instrument within the body. Therefore, it would have been obvious to one having ordinary skill in the art to have modified Soble with a sensor to easily navigate the instrument through the body to the correct location. It is also well known in the art to provide scales on devices in order to determine the position of the device. Examples of such scales are depth-locators on cutters, syringes, and stereotaxic devices. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Soble with a scale in order to determine the position of the instrument relative to the stabilizer. With further respect to claim 93, it would have been obvious to one having ordinary skill in

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the art at the time the invention was made to provide the sealing ring at the distal end of the device, since it has been held that a mere rearrangement of the essential working parts of a device involves only routine in the art. With further respect to claim 97, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shape of the loop as a matter of design choice, if the application required such a shape. With further respect to claims 100-104, Soble discloses the nozzles may be used to deliver fluids, in which adhesives are well known in the art for sealing tissue. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device with adhesives as recited in the claims if one desired to seal tissue openings. With further respect to claims 111 and 112, valves are well known in the art for providing a sealing relationship between parts of a surgical instrument. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include one or more valves in Soble's assembly to provide a sealing relationship between instruments.

**Claims 77-79, 94, and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soble et al. in view of Abrams et al. (U.S. Patent No. 6,740,098 B2).** Soble discloses the claimed invention, except for a fixing device as claimed. Abrams discloses a stabilizer, instrument [applicator], and fixing device (see entire document). Abrams teaches the fixation device comprises a tubular member comprising flange fingers having openings capable of being bent (for example, see Figure 31) and carried on the head section of the instrument (for example, see Figure 8). It would have

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been obvious to one having ordinary skill in the art at the time the invention was made to include a fixing device in Soble's assembly as taught by Abrams in order to be able to utilize the device for wound closure. With further respect to claim 95, heart valves are well known in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the assembly with a heart valve prosthesis if one desired to utilize the assembly for treating a heart valve.

**Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soble et al. and Abrams et al. as applied to the claims above, and further in view of Gifford, III (U.S. Patent No. 5,695,504).** Soble as modified by Abrams discloses the claimed invention except for an instrument [applicator] that includes an elongated support member and support ring, and an obstructing member. Gifford discloses an assembly comprising an instrument [applicator] (118) capable of fixing a fixing device. Gifford teaches the instrument [applicator] includes an elongated support member (124), a support ring (102) located at the distal end of the elongated member and capable of being positioned inside a fixing device (for example, see Figure 5F), and an obstructing member (125) that is capable of moving as claimed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize Gifford's instrument in the assembly of Soble as modified by Abrams if the procedure being performed required tissue clamping.

**Claims 98 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soble in view of Moenning (U.S. Patent No. 5,725,553).** Soble discloses the claimed invention except for a flange on the stabilizer. Moenning discloses a stabilizer

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(see entire document). Moenning teaches a flange on the stabilizer for contacting tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Soble's stabilizer with a flange as taught by Moenning. Doing so would provide a means for sealing the stabilizer with surrounding tissue during use.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is (571)272-9062. The examiner can normally be reached on Monday through Friday 7-7 (max flex).



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson /M. T./  
Examiner, Art Unit 3773  
February 3, 2010

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773